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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,871	06/04/1998	RUDOLF CAROLUS MARIA BARENDSE		3289
23416 7590 09/30/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 10000			EXAMINER	
			RAMIREZ, DELIA M	
WILMINGTON, DE 19899			ART UNIT	PAPER NUMBER
			1652	
			MAIL DATE	DELIVERY MODE
			09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
Office Action Occurrence	09/089,871	BARENDSE ET AL.			
Office Action Summary	Examiner	Art Unit			
	DELIA M. RAMIREZ	1652			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ Responsive to communication(s) filed on <u>04 Au</u>	iaust 2008				
	action is non-final.				
·=		secution as to the merits is			
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
closed in accordance with the practice under L	x parte Quayle, 1955 C.D. 11, 40	0.0.213.			
Disposition of Claims					
<ul> <li>4) Claim(s) 18,19,21,22,24,26-28,31-35,41-46,48 and 50-52 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5) Claim(s) is/are allowed.</li> <li>6) Claim(s) 18,19,21,22,24,26-28,31-35,41-46,48 and 50-52 is/are rejected.</li> <li>7) Claim(s) is/are objected to.</li> <li>8) Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 8/4/08.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal Pa 6)  Other:	ite			

## **DETAILED ACTION**

# Status of the Application

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48 and 50-52 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/4/2008 has been entered.

Applicant's amendment of claim 31 as submitted in a communication filed on 8/4/2008 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/4/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

## Claim Rejections - 35 USC § 112, Second Paragraph

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 4. Claims 18-19 remain indefinite in the recitation of "increased pelleting stability" for the reasons of record and those set forth below. See the Non Final action mailed on 7/27/2007 and Final action mailed on 5/6/2008 for detailed discussion of this rejection.
- 5. Applicant cites the MPEP to point out that (1) the test for definiteness is whether one of skill in the art would understand what is claimed when read in light of the specification, and (2) the meaning of a term may be defined according to the usage of the term in context in the specification. According to Applicant, the term "pelleting stability" as used in the claims is defined by implication according to the usage of the term in the specification. Applicant also argues that Applicant has indicated how to interpret the claim in the response filed on 1/24/2008, citing a declaration and references previously submitted in support of this interpretation.
- Applicant's arguments have been fully considered but are not deemed persuasive to 6. overcome the instant rejection. The examiner acknowledges the citations made by Applicant as set forth in the MPEP regarding definiteness as well as previously submitted references and a declaration by Dr. Lutz End. The references and End declaration submitted with the response filed 1/24/2008 have been previously addressed and were not found persuasive for the reasons of record extensively discussed in the Office action mailed on 5/6/2008. Briefly, none of the references provided except for one, uses the term "pelleting stability" as equivalent to "stability of an enzyme after pelleting", which is the interpretation Applicant has indicated as their intended interpretation in the response of 1/24/2008. As such, the argument that one of skill in the art would reasonably conclude that the meaning of the term "pellelting stability" as equivalent to "stability of an enzyme after pelleting" is the most common meaning of the term in the art was not found persuasive. With regard to the MPEP citations made by Applicant, it is noted that the Examiner agrees that one should take the specification into account when determining definiteness. However, as indicated previously, even if the assumption is made that Applicant's interpretation of the term "pelleting stability" has been used by others, the term has a more

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apparent interpretation, i.e., stability of the pellet after the pelleting process. While not required, one could observed higher enzyme stability in pellets that have higher structural stability. Thus, an indication that a pellet has higher enzyme stability and pelleting stability does not necessarily imply that the term "pelleting stability" is equivalent to "stability of the enzyme after pelleting". Therefore, in the absence of a definition as to the intended meaning of the term, Applicant's usage of the term in the specification would not necessarily convey applicant's intended meaning to one of ordinary skill in the art. In addition, as previously indicated, even if it is assumed that the term "pelleting stability" as used in the claims is definite, it is reiterated herein that the term "increased pelleting stability" is unclear and confusing in the absence of a basis for comparison (i.e., increased with respect to what?). Therefore, for the reasons of record and those set forth above, one cannot reasonably conclude that the claim are definite.

# Claim Rejections - 35 USC § 103

- 7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 8. Claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48, 50-52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996).
- 9. Claims 22, 46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48, 50-52 above, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978).
- Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 remain rejected under 35 U.S.C. 10. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of

Ghani (U.S. Patent No. 6120811, filed 10/4/1996), and further in view of Haarasilta (GB 2-139868A, 1984).

- 11. These rejections have been discussed at length in previous Office actions and they are maintained for the reasons of record and those set forth below.
- 12. Applicant argues that the preamble should be given patentable weight to distinguish the claimed invention from the prior art. Specifically, Applicant argues that the term "pelleting stability" should be given patentable weight because the term gives "life, meaning, and vitality" to the claim. Applicant asserts that since the Examiner in the action mailed on 5/6/2008 has indicated that the property recited in the claim, i.e., increased pelleting stability, is a property required in the claimed product, the term should be given patentable weight. Applicant argues that Nielsen suggests that the phytase be added after pelleting, whereas the specification teaches adding the phytase prior to pelleting for increased pelleting stability. Applicant also submits that none of the additional references by Ghani, Markussen or Haarasilta teach or suggest adding the phytase prior to pelleting. Applicant also argues that the Examiner should read the claims by evaluating the invention as a whole, i.e, the particular granulate claimed and disclosed in the specification. With regard to inherency, Applicant argues that (1) it is well established that the inherency of missing features/limitations is limited to the context of anticipation under 35 USC 102, (2) inherency may not be established by probabilities or possibilities, (3) obviousness cannot be predicated on what is unknown even if the inherency of a certain feature is later established. Applicant points out that since none of the references cited by the examiner discuss pelleting stability, there is no basis for obviousness. In making an analogy to the findings of *In re Antonie*, Applicant states that the references cited by the Examiner did not recognize that increased pelleting stability was a function of the high activity phytase-containing granulate as claimed.
- Applicant's arguments have been fully considered but are not deemed persuasive to 13. overcome the instant rejection. For the record, the Examiner's statement on page 5, item 13 of

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the Office action mailed on 5/6/2008, cited by Applicant as evidence to show that the term "increased pelleting stability" should be given patentable weight, reads as follows:

The Examiner acknowledges Applicant's citation of case law and the MPEP, as well as arguments regarding the patentable weight of the term "pelleting stability". However, the Examiner disagrees with Applicant's contention that in the instant case, inherency has been used as substitute for teaching/suggestion/motivation to combine the cited references. Applicant is reminded that the Examiner has never made the argument that one of skill in the art would have been motivated to combine the teachings of Nielsen, Ghani, Haarasilta and Markussen to obtain a granulate with "higher pelleting stability". Thus, Applicant's arguments regarding the improper use of inherency in the obviousness rejection applied are not deemed persuasive and irrelevant to the issue at hand. It is reiterated herein that the "inherency" argument made is in reference to a property/characteristic required in the claimed product, which the specification and applicant suggest as being a property of any granulate having the same phytase activity as that of the granulate of Nielsen et al., i.e., at least 6000 FTU/gram. For the reasons extensively discussed above, the term "increased pelleting stability" has not been given any patentable weight. However, even if the term were to be given patentable weight, it is reiterated herein that Applicant has argued throughout the prosecution of the instant application that it is the high phytase activity of the granulate, namely at least 6000 FTU/gram, which results in higher stability of the phytase in the pellet, and not the identity of the phytase used in the granulate. Thus, based on Applicant's own arguments, any phytase granulate wherein the phytase activity is at least 6000 FTU/gram would have the recited "increased pelleting stability". In view of the fact that the granulate of Nielsen alone has at least 6000 FTU/gram, and neither the specification nor the art teach that the carrier/hydrophobic/gel-forming/water insoluble compound has any effect on the stability of the phytase after pelleting, one of skill in the art would have to conclude that the granulate of Nielsen, Ghani, Markussen and Haarasilta would meet the desired limitation.

Clearly, the statement regarding a property/characteristic required in the claimed product, when read within the context of the entire paragraph, is not an admission that the term "increased pelleting stability" should be given patentable weight. Instead, the Examiner is rebutting Applicant's arguments regarding inherency by indicating that inherency can be properly used in the instant case because inherency is not being used to provide motivation to combine the references but to show that Applicant's asserted property for the claimed pellet as stated in the response of 1/24/2008 (i.e., increased phytase stability) is inherent to the pellet of Nielsen in view of the fact that the granulate of Nielsen alone has at least 6000 FTU/gram, which is the characteristic that applicant throughout the prosecution of this case has indicated as the reason why the granules of the invention have higher phytase stability. It is reiterated herein that even if

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the term "increased pelleting stability" were to be given patentable weight, it is Applicant's own arguments throughout the prosecution of this case that support the Examiner's conclusion of inherency with regard to phytase stability in the pellets.

With regard to arguments that Nielsen suggests adding the phytase after the pelleting process and that none of the additional references cited teach adding the phytase before pelleting, it is noted that (1) Example 3 of Nielsen is one of the many teachings regarding the use of phytases in animal feed, and (2) Nielsen specifically and explicitly teaches an animal feed additive which is a granulated enzyme product (page 10, third paragraph). Therefore, contrary to Applicant's argument, Example 3 of Nielsen is not evidence that shows that Nielsen teaches away from adding the phytase prior to pelleting in view of the fact that Nielsen clearly teaches granules already having the phytase in them.

Applicant's arguments regarding the use of inherency in obviousness rejections. As discussed above, and extensively discussed in the previous Office action, the Examiner is not using inherency to show motivation to combine the references cited. The cited case law is acknowledged, however, contrary to applicant's assertions, the instant case is not analogous to *In re Antonie* because the Examiner is not contending that it would be obvious to combine the teachings of the cited art to obtain granules that have enhanced phytase activity after pelleting by making granules which have a phytase activity of at least 6000 FTU/gram. It is reiterated herein that granules that have at least 6000 FTU/gram are taught by **Nielsen alone** and Applicant has repeatedly indicated that it is because of this level of phytase activity that the granulate of the invention has enhanced phytase stability. Therefore, one would have to conclude that the granulate of Nielsen would inherently have enhanced phytase activity because it meets the phytase activity limitation required for enhanced phytase stability **as repeatedly stated by Applicant**. The teachings of Ghani, Markussen and Haarasilta have been introduced as

references which render limitations other than the level of phytase activity in the granulate obvious over the teachings of Nielsen. As such, neither Nielsen nor Ghani, Markussen and Haarasilta have to teach increased "pelleting stability" as a function of the phytase activity in the granulate for them to render the claimed invention obvious over the prior art of record.

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With regard to Applicant's arguments traversing the Examiner's broad interpretation given to the claims, it is noted that the Examiner has interpreted the claims in accordance to MPEP 2106(II)(C), which clearly states that USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). In the instant case, it has been repeatedly indicated to Applicant that even if patentable weight is given to the term "increased pelleting stability" and the Examiner assumes that the term "increased pelleting stability" reads "higher phytase activity in the granulate after pelleting", the granulate of Nielsen alone would meet this limitation in view of applicant's own assertions. Therefore, for the reasons extensively discussed above and in previous Office actions, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

#### Conclusion

- 14. No claim is in condition for allowance.
- All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action

after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashaat Nashed can be reached on (571) 272-0934. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Delia M. Ramirez/

Delia M. Ramirez, Ph.D. Primary Patent Examiner Art Unit 1652

DR October 7, 2008